

WHAT IS CLAIMED:

1. A method of manipulating the temperature of a patient comprising steps of:

- 5 positioning a balloon catheter in the stomach of the patient;
 exchanging heat between the balloon catheter and the stomach so as to
 controllably alter the temperature of a substantial portion of the patient's body.

- 10 2. The method of claim 1, wherein the step of exchanging heat between
 the balloon catheter and the stomach further includes introducing a heat exchange
 fluid into the balloon catheter.

- 15 3. The method of claim 2, further comprising maintaining the heat
 exchange fluid at a temperature different from normothermia.

4. The method of claim 2, further comprising maintaining the heat
 exchange fluid at a temperature different from normothermia for a period of time
 sufficient to modify the core body temperature of the patient.

- 20 5. The method of claim 2, further comprising maintaining the heat
 exchange fluid at a temperature above normothermia.

6. The method of claim 2, further comprising maintaining the heat
 exchange fluid at a temperature below normothermia.

- 25 7. The method of claim 1, wherein the step of exchanging heat between
 the balloon catheter and the stomach further includes introducing a liquid into the
 balloon catheter.

8. The method of claim 1, wherein the step of exchanging heat between the balloon catheter and the stomach further includes introducing a gas into the balloon catheter.

5 9. The method of claim 1, further comprising: introducing the balloon catheter through the esophagus of the patient before positioning the balloon catheter in the stomach of the patient, wherein the balloon catheter includes a catheter shaft having a diameter significantly less than the diameter of the esophagus.

10 10. The method of claim 1, further comprising expanding the balloon catheter in the stomach, wherein the expanded balloon catheter generally conforms with the size and shape of the stomach.

11 11. The method of claim 1, further comprising expanding the balloon
15 catheter in the stomach, wherein the expanded balloon catheter distends the stomach.

12. The method of claim 1, further comprising: maintaining a
predetermined target temperature for the patient that is different from
20 normothermia.

13. The method of claim 12, further comprising: returning the patient to
normothermia after the step of maintaining the predetermined target temperature for
the patient.

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14. The method of claim 1, further comprising:
monitoring the patient with a temperature probe to obtain a monitored
temperature;

controlling the step of exchanging heat between the balloon catheter automatically based on the monitored temperature of the patient.

15. The method of claim 1, further comprising: administering an
5 anti-shivering mechanism to the patient during the step of exchanging heat between the balloon catheter and the stomach.

16. The method of claim 15, wherein the step of administering the
anti-shivering mechanism includes administering a therapeutically effective amount
10 of an anti-shivering agent to the patient.

17. The method of claim 15, wherein the step of administering the
anti-shivering mechanism includes administering a therapeutically effective amount
of an anti-shivering agent to the patient and applying warmth to the skin of the
15 patient.

18. A method of manipulating the temperature of a patient comprising
steps of:

positioning a balloon catheter in the stomach of the patient,
20 introducing a heat exchange fluid into the balloon catheter; and
allowing the heat exchange fluid to flow through the balloon catheter in a
closed-loop, wherein heat is exchanged between the balloon catheter and the
stomach so as to controllably alter the temperature of at least a portion of the
patient.

25 19. The method of claim 18, wherein the heat exchange fluid flows
continuously in the step of allowing the heat exchange fluid to flow through the
balloon catheter in a closed-loop.

20. The method of claim 18, maintaining the heat exchange fluid at a temperature different from normothermia for a period of time sufficient to modify the core body temperature of the patient.

5 21. The method of claim 18, further comprising maintaining the heat exchange fluid at a temperature below normothermia.

22. The method of claim 18, further comprising maintaining the heat exchange fluid at a temperature below zero degrees centigrade.

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23. The method of claim 18, wherein the heat exchange fluid is a liquid.

24. The method of claim 18, wherein the heat exchange fluid is a gas.

15 25. The method of claim 18, further comprising maintaining the heat exchange fluid at a temperature above normothermia.

26. The method of claim 18, further comprising: introducing the balloon catheter through the esophagus of the patient before positioning the balloon catheter
20 in the stomach of the patient, wherein the balloon catheter includes a catheter shaft having a diameter significantly less than the diameter of the esophagus.

27. The method of claim 18, wherein the step of introducing the heat exchange fluid into the balloon catheter further includes expanding the balloon
25 catheter to generally conform with the size and shape of the stomach.

28. The method of claim 18, wherein the step of introducing the heat exchange fluid into the balloon catheter further includes expanding the balloon catheter to distend the stomach.

29. The method of claim 18, wherein the balloon catheter is in contact with the stomach during the step of allowing the heat exchange fluid to flow continuously through the balloon catheter.

5 30. The method of claim 18, further comprising: maintaining a predetermined target temperature for the patient that is different from normothermia.

10 31. The method of claim 30, further comprising: returning the patient to normothermia after the step of maintaining the predetermined target temperature for the patient.

15 32. The method of claim 18, further comprising:
monitoring the patient with a temperature probe to obtain a monitored temperature;
controlling the step of exchanging heat between the balloon catheter automatically based on the monitored temperature of the patient.

20 33. The method of claim 18, further comprising: administering an anti-shivering mechanism to the patient during the step of exchanging heat between the balloon catheter and the stomach.

25 34. The method of claim 33, wherein the step of administering the anti-shivering mechanism includes administering a therapeutically effective amount of an anti-shivering agent to the patient.

35. The method of claim 33, wherein the step of administering the anti-shivering mechanism includes administering a therapeutically effective amount

of an anti-shivering agent to the patient and applying warmth to the skin of the patient.

36. A method of manipulating the temperature of a patient comprising
5 steps of:

introducing a balloon catheter through the esophagus of the patient, wherein
the balloon catheter includes a catheter shaft having a distal end, a balloon located
on the distal end of the catheter shaft, and the catheter shaft includes a first lumen in
fluid communication with the balloon and a second lumen in fluid communication
10 with the balloon;

positioning the balloon in the stomach of the patient,
expanding the balloon with a heat exchange fluid delivered through the first
lumen into the balloon and out of the balloon through the second lumen, wherein
heat is exchanged between the balloon and the stomach so as to controllably alter
15 the temperature of at least a portion of the patient.

37. The method of claim 36, wherein the heat exchange fluid flows
continuously in a closed-loop through the first lumen into the balloon and out of the
balloon through the second lumen in the step of expanding the balloon.

38. The method of claim 36, wherein the expanded balloon generally
conforms with the stomach in the step of expanding the balloon.

39. The method of claim 36, wherein the expanded balloon distends the
25 stomach in the step of expanding the balloon.

40. The method of claim 36, maintaining the heat exchange fluid at a
temperature different from normothermia for a period of time sufficient to modify
the core body temperature of the patient.

41. The method of claim 36, further comprising maintaining the heat exchange fluid at a temperature below normothermia.

5 42. The method of claim 36, further comprising maintaining the heat exchange fluid at a temperature below zero degrees centigrade.

43. The method of claim 36, wherein the heat exchange fluid is a liquid.

10 44. The method of claim 36, wherein the heat exchange fluid is a gas.

45. The method of claim 36, further comprising maintaining the heat exchange fluid at a temperature above normothermia.

15 46. The method of claim 36, further comprising: maintaining a predetermined target temperature for the patient that is different from normothermia.

47. The method of claim 46, further comprising: returning the patient to normothermia after the step of maintaining the predetermined target temperature for the patient.

48. The method of claim 36, further comprising:
monitoring the patient with a temperature probe to obtain a monitored
25 temperature;
controlling the step of exchanging heat between the balloon catheter automatically based on the monitored temperature of the patient.

49. The method of claim 36, further comprising: administering an anti-shivering mechanism to the patient during the step of exchanging heat between the balloon catheter and the stomach.

5 50. The method of claim 49, wherein the step of administering the anti-shivering mechanism includes administering a therapeutically effective amount of an anti-shivering agent to the patient.

10 51. The method of claim 49, wherein the step of administering the anti-shivering mechanism includes administering a therapeutically effective amount of an anti-shivering agent to the patient and applying warmth to the skin of the patient.

15 52. A heat exchange apparatus comprising:
a first fluid lumen having a distal end and a second fluid lumen having a distal end;
a balloon in fluid communication with the distal end of the first fluid lumen and the distal end of the second fluid lumen, wherein a heat exchange fluid is delivered into the balloon through the first fluid lumen and the heat exchange fluid
20 is circulated out of the balloon through the second fluid lumen;
wherein heat is exchanged between the stomach and the heat exchange fluid circulating in the balloon so as to controllably alter the temperature of at least a portion of the patient.

25 53. The apparatus according to claim 52, wherein the balloon comprises a thin-walled, high strength, thermoplastic material, readily inflatable under fluid pressure and readily collapsible under vacuum.

54. The apparatus according to claim 52, wherein the material of the balloon comprises polyethylene terephthalate.

55. The apparatus according to claim 52, wherein the balloon is
5 expandable to approximate the shape of the stomach.

56. The apparatus according to claim 52, wherein the balloon comprises an elastic material.

10 57. The apparatus according to claim 52, wherein the balloon is configured to generally conform with the stomach when the balloon is expanded.

58. The apparatus according to claim 52, wherein the first fluid lumen is coaxial with the second fluid lumen.

15 59. The apparatus according to claim 52, wherein the first fluid lumen is side-by-side with the second fluid lumen.

60. The apparatus according to claim 52, wherein when the balloon is
20 expanded by the delivered heat exchange fluid, the expanded balloon substantially conforms with the stomach.

61. The apparatus according to claim 52, further comprising a temperature sensor located adjacent to the balloon.

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62. The apparatus according to claim 52, further comprising a thermoelectric heat exchanger connected to the first fluid lumen, wherein the thermoelectric heat exchanger controls the temperature of the heat exchange fluid flowing to the first fluid lumen.

63. The apparatus according to claim 62, wherein the thermoelectric heat exchanger includes a temperature probe, and the thermoelectric heat exchanger is automatically controlled based on signals received from the temperature probe.

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